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EXAMINER

VO, HAI

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

1. Applicants are reminded of their right to request rejoinder of method claims with the product claims upon indication of the product claims as being allowable. The method claims must be commensurate with the allowed article claims, i.e. have been amended to recite all the features of the allowed article claims. See *In re Ochiai* 37 USPQ2d 1127.
2. Objections of claims 17-19 have been withdrawn in view of the present amendment.
3. The art rejections over Ito et al. (US 2005/0049715), Ochi (US 2002/0022885) and Imura et al. (US 6,340,648) have been withdrawn in view of the present amendment. None of cited references teach or suggest the walls defining within the material being hollow. However, the art rejections over Heidi et al. (US 2002/0165616) are maintained. New grounds of rejections are made in view of newly discovered references to EP 254 557, Twigg et al. (US 4,810,685) and Zhang et al. (US 2005/0158535).

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 14, 15, 17-19 and 51 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Heide et al. (US 2002/0165616). Since the foam material is completely removed from the final product of the present invention, a porous sintered ceramic does not contain any foam materials. Heide teaches a bone substitute material comprising tubular macropores oriented in at least one direction corresponding to a biomechanically or biofunctionally intended direction of growth (paragraphs 45-48). This at least indicates that the tubular macropores have a length in one direction greater than a length in a perpendicular direction. The tubular macropores which is formed by means of milling or drilling have a diameter ranging from 100 to 2000 microns. The bone substitute material further includes a matrix of micropores (paragraph 39). This is a clear indication that the walls surrounding the tubular macropores will be hollow due to the presence of the micropores thereon. The material has a macroporosity in the range of 25 to 50% by volume which is overlapping with the claimed range (paragraph 54). Heide does not specifically disclose the material having a breaking stress of more than 1 MPa. However, it appears that the

material meets all the structural limitations and chemistry required by the claim.

The bone substitute material comprises tubular pores oriented in at least one direction corresponding to a biomechanically or biofunctionally intended direction of growth. This at least indicates that the pores have a length in one direction greater than a length in a perpendicular direction. The tubular pores have a diameter ranging from 100 to 2000 microns. The walls defining the tubular pores within the material are hollow. The material has a macroporosity in the range of 25 to 50% by volume. Therefore, it is the examiner's position that the breaking stress would be inherently present. This is in line with *In re Spada*, 15 USPQ 2d 1655 (1990) which holds that products of identical chemical composition can not have mutually exclusive properties. It seems from the claim, if one meets the structure recited, the properties must be met or Applicant's claim is incomplete. Accordingly, Heide anticipates or strongly suggests the claimed subject matter.

7. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Heide et al. (US 2002/0165616). Heide does not specifically disclose the tubular pores having a length in one direction more than 20% greater than their length in the two other perpendicular directions. Since the diameter/length ratio is recognized as a result-effective variable, differences in the diameter/length ratio will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such diameter/length ratio is critical or provides unexpected results. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have the tubular

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pores with the diameter/length ratio in the range instantly claimed motivated by the desire to facilitate the rapid in-growth of bony tissues without compromising the mechanical strength of the implant.

8. The art rejections over Heide have been maintained for the following reasons.

Applicants contend that Heide does not teach or suggest an inventive method of making a bone substitute material set forth in the claimed invention, Heide fails to contemplate the claimed hollow walls. The examiner respectfully disagrees.

Heide teaches a bone substitute material comprising tubular macropores oriented in at least one direction corresponding to a biomechanically or biofunctionally intended direction of growth (paragraphs 45-48). The tubular macropores have a wall thickness in the range from 1500 to 4000 microns (claim 13). The bone substitute material further includes a matrix of micropores (paragraph 39). This is a clear indication that the walls surrounding the tubular macropores will be hollow due to the presence of the micropores thereon. Note that nothing in the claims is specific about a double wall defining the open cell is hollow. Accordingly, the art rejections are sustained.

9. Claims 14-16 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over EP 254 557. EP'557 teaches a filter of a porous sintered ceramic body having approximately the form of a positive image of an open celled foam material (example 1). Since EP'557 uses the same approach as disclosed in the present invention to form the porous sintered ceramic body, the walls defining the cells within the material will be

inherently hollow due to removal of the foam material during sintering. The foam cells are elongated with the ratio b/a of the average major axis b to the average minor axis a of the cells of 1.9 (example 1). The recitation that the article is a "bone substitute material" has not given patentable weight because it has been held that a preamble is denied the effect of a limitation where the claim is drawn to a structure and the portion of the claim following the preamble is a self-contained description of the structure not depending for completeness upon the introductory clause, *Kropa v. Robie*, 88 USPQ 478 (CCPA 1951). Accordingly, EP'557 anticipates or strongly suggests the claimed subject matter.

10. Claim 51 is rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Zhang et al. (US 2005/0158535). Zhang teaches a bone substitute material of a porous sintered ceramic body having approximately the form of a positive image of an open celled foam material (paragraphs 62 and 63). Since Zhang uses the same approach as disclosed in the present invention to form the porous sintered ceramic body, the walls defining the cells within the material will be inherently hollow due to removal of the foam material during sintering. The material has a macroporosity in the range of 40 to 78%, a compressive strength ranging from 5 MPa to 10 MPa and an average pore size of 100 to 300 microns (paragraphs 37 and 40). Accordingly, Zhang anticipates or strongly suggests the claimed subject matter.

11. Claims 14-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang et al. (US 2005/0158535) in view of EP 254 557. Zhang teaches a filter of a porous sintered ceramic body having approximately the form of a positive image of an open celled foam material (paragraphs 62 and 63). Since Zhang uses the same approach as disclosed in the present invention to form the porous sintered ceramic body, the walls defining the cells within the material will be inherently hollow due to removal of the foam material during sintering. The material has a macroporosity in the range of 40 to 78%, a compressive strength ranging from 5 MPa to 10 MPa and an average pore size of 100 to 300 microns (paragraphs 37 and 40). Zhang does not specifically disclose the foam pores being oriented in a manner such that the foam pores have a length in one direction greater than a length in a perpendicular direction. EP'557, however, teaches a filter of a porous sintered ceramic body having approximately the form of a positive image of an open celled foam material (example 1). The foam cells are elongated with the ratio b/a of the average major axis b to the average minor axis a of the cells of 1.9 (example 1). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have the foam pores oriented in a manner as taught by EP'557 motivated by the desire to provide a great reducing effect on pressure loss while maintaining the purifying capacity.

12. Claims 14-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Twigg et al. (US 4,810,685) in view of EP 254 557. Twigg discloses a filter

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comprising a ceramic foam having approximately the form of a positive image of an open celled foam material by impregnation of the foam material with a ceramic slurry, followed by drying and firing the impregnated foam to remove the foam material and to cause the ceramic material to sinter (abstract). Likewise, it is clearly apparent that the walls defining the cells within the catalyst will be inherently hollow as the same approach for making a porous sintered ceramic material is employed. The filter has a porosity of 64%, an average pore size in the range 20 to 300 microns (abstract, example 1). Since the breaking stress is dictated by the porosity and pore size, it is not seen that the breaking stress could be outside the claimed range as the porosity and pore size are within the claimed ranges. Twigg does not specifically disclose the foam pores oriented in a manner such that the foam pores have a length in one direction greater than a length in a perpendicular direction. EP'557, however, teaches a filter of a porous sintered ceramic body having approximately the form of a positive image of an open celled foam material (example 1). The foam cells are elongated with the ratio b/a of the average major axis b to the average minor axis a of the cells of 1.9 (example 1). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have the foam pores oriented in a manner as taught by EP'557 motivated by the desire to provide a great reducing effect on pressure loss while maintaining the purifying capacity. Note that, the recitation that the article is a "bone substitute material" has not given patentable weight because it has been held that a preamble is denied the effect

of a limitation where the claim is drawn to a structure and the portion of the claim following the preamble is a self-contained description of the structure not depending for completeness upon the introductory clause, *Kropa v. Robie*, 88 USPQ 478 (CCPA 1951).

13. Claim 51 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Twigg et al. (US 4,810,685). Twigg discloses a filter comprising a ceramic foam having approximately the form of a positive image of an open celled foam material by impregnation of the foam material with a ceramic slurry, followed by drying and firing the impregnated foam to remove the foam material and to cause the ceramic material to sinter (abstract). Likewise, it is clearly apparent that the walls defining the cells within the filter will be inherently hollow as the same approach for making a porous sintered ceramic material is employed. The filter has a porosity of 64%, an average pore size in the range 20 to 300 microns (abstract, example 1). Since the breaking stress is dictated by the porosity and pore size, it is not seen that the breaking stress could be outside the claimed range as the porosity and pore size are within the claimed ranges. Note that, the recitation that the article is a "bone substitute material" has not given patentable weight because it has been held that a preamble is denied the effect of a limitation where the claim is drawn to a structure and the portion of the claim following the preamble is a self-contained description of the structure not depending for completeness upon the

introductory clause, *Kropa v. Robie*, 88 USPQ 478 (CCPA 1951). Accordingly, Twigg anticipates or strongly suggests the claimed subject matter.

Conclusion

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hai Vo whose telephone number is (571) 272-1485. The examiner can normally be reached on Monday through Thursday, from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Callie Shosho can be reached on (571) 272-1123. The

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fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Hai Vo/
Primary Examiner, Art Unit 1794